

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY
PROLIANCE SURGEONS, INC. PS PROPOSING TO ESTABLISH AN AMBULATORY
SURGERY CENTER IN SKAGIT COUNTY**

PROJECT DESCRIPTION

Proliance Surgeons, Inc., P.S. (PS, Inc.) is a Washington State corporation comprised of care centers, ambulatory surgery centers (ASCs), physical therapy, occupational therapy, and magnetic resonance imaging (MRI) facilities. Of these various types of healthcare facilities, only the ASCs are subject to state survey and regulations. PS, Inc. manages and operates 33 physician offices, which are located within King, Pierce, Skagit, and Snohomish counties. Of the 33 physician offices, six have ASCs associated with them. The chart below illustrates the six existing PS, Inc. ASCs. [source: CN historical files and PS, Inc. website]

County	Surgery Centers/City Location
King	Evergreen Orthopedic Surgery Center/Kirkland
	Evergreen Surgical Clinic/Kirkland
	Issaquah Surgery Center/Issaquah
	Valley Orthopedic Associates/Renton
Skagit	Skagit Island Orthopedic Surgery Center/Mount Vernon
Snohomish	Edmonds Center for Outpatient Surgery/Edmonds

This application focuses on the ASC located in Skagit County, known as Skagit Island Orthopedic Surgery Center (in bold above). On April 4, 2003, the department granted an exemption to PS, Inc. for the establishment of this ASC located at 1401 South LaVenture Avenue in the city of Mount Vernon, within Skagit County. The exempt ASC received Medicare certification in August 2003, with two operating rooms (ORs), one procedure room, and support/staff areas. [source: CN historical files and Application, p5]

As an exempt ASC, only those physicians part of the Proliance corporation are allowed access to the ASC. Currently, the surgeries performed at Skagit Island Orthopedic Surgery Center are solely orthopedic. The five Proliance physicians that perform surgeries at the exempt ASC are Gary Clancey, MD; Daniel Hanesworth, MD; Leonard Kolodychuk, MD; Curtis Rodin, MD; and Richard Williamson, MD. [source: Application, p3]

In addition to the five orthopedic physicians above, two additional physicians practice at Skagit Island Orthopedic Surgery Center, but do not perform surgeries. The two physicians are Jimmy Cui, MD, a physiatrist; and Randolph Anderson, MD a podiatrist. [source: Application, p3]

This application proposes to open Skagit Island Orthopedic Surgery Center to other physicians that are not part of the Proliance corporation. PS, Inc. indicates that local surgeons have requested access to the ASC, and if this project is approved, the ASC may offer podiatry, pain management, and ophthalmology in addition to orthopedic surgeries. [source: April 17, 2006, supplemental information, p3]

When an exempt ASC is established within twelve months before an application is submitted, the department requires the applicant to identify the capital costs for its establishment. Those costs are then used to determine the estimated capital expenditure of the project, even though the costs may already be

expended. As previously stated, Skagit Island Orthopedic Surgery Center became operational in August 2003. While PS, Inc. identified the costs to establish the exempt ASC to be \$2,076,807, given that the ASC has been operational for three years, the department will consider the capital costs to be zero. [source: Application, pp 1 & 28]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

APPLICATION CHRONOLOGY

November 21, 2005	Letter of Intent Submitted
February 8, 2006	Application Submitted
February 9, 2006	Department's Pre-Review Activities
through April 24, 2006	<ul style="list-style-type: none">• 1st screening activities and responses• 2nd screening activities and responses
April 25, 2006	Department Begins Review of the Application
	<ul style="list-style-type: none">• public comments accepted throughout review
May 30, 2006	Public Hearing Conducted/End of Public Comment
June 14, 2006	Rebuttal Documents Received at Department
August 1, 2006	Department's Anticipated Decision Date
July 31 2006	Department's Actual Decision Date

AFFECTED PARTIES

Throughout the review of this project, two entities sought and received affected person status under WAC 246-310-010. Both entities are existing hospitals located in Skagit County and are listed below.

- Skagit Valley Hospital, located in the city of Mount Vernon; and
- United General Hospital located in the city of Sedro Woolley.

SOURCE INFORMATION REVIEWED

- Skagit Island Orthopedic Surgery Center's Certificate of Need Application submitted February 8, 2006
- Skagit Island Orthopedic Surgery Center's supplemental information dated April 17, 2006, and May 1, 2006
- Public comment received throughout the review of the application
- Public hearing documents received at the May 30, 2006, public hearing
- Rebuttal comments provided by Skagit Island Orthopedic Surgery Center dated June 14, 2006¹
- Skagit County ASC and/or operating room utilization survey responses
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2002, 2003, and 2004 summaries)

¹ Neither Skagit Valley Hospital nor United General Hospital submitted rebuttal responses.

SOURCE INFORMATION REVIEWED (continued)

- Population data obtained from the Office Financial Management based on year 2000 census published January 2002.
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Data obtained from the Internet regarding health care worker shortages in Washington State
- Data obtained from the Internet regarding mileage and distance
- Data obtained from the Medical Assistance Administration concerning Medicaid contracts
- Certificate of Need Historical files

CRITERIA EVALUATION

To obtain Certificate of Need approval, the applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment) and WAC 246-310-270 (ambulatory surgery).²

CONCLUSION

For the reasons stated in this evaluation and agreement to the following term, Proliance Surgeons, Inc.'s application is approved to establish an ambulatory surgery center in the city of Mount Vernon within Skagit County.

Before commencement of the project, Proliance Surgeons, Inc. must provide to the department for review and approval a copy of the revised Admissions Policy for Skagit Island Orthopedic Center. The revised policy must include language ensuring all patients, including low-income, racial and ethnic minorities, handicapped and other underserved groups would have access to surgical services.

Provided that the applicant agrees to the term outlined above, a Certificate of Need would be issued with the conditions below.

1. Proliance Surgeons, Inc. will ensure that Skagit Island Orthopedic Surgery Center will provide charity care in compliance with the charity care policy provided in the application and the requirements of the applicable law. Skagit Island Orthopedic Surgery Center will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by the two hospitals located in the east Skagit planning area during the three most recent years. For historical years 2002-2004, these amounts are 1.61% of gross revenues and 3.36% of adjusted revenues. Skagit Island Orthopedic Surgery Center will maintain records documenting the amount of charity care it provides and demonstrating compliance with its charity care policy and applicable law.

² Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-220(3); and WAC 246-310-240(2) and (3).

2. Skagit Island Orthopedic Surgery Center will maintain its participation in the Medicaid Program by maintaining its existing contract with Department of Socials and Health Services.

The facility, Skagit Island Orthopedic Surgery Center, is located in the east Skagit planning area. There is no capital expenditure associated with this project.

A. Need (WAC 246-310-210)

Based on the source information reviewed and subject to the term and conditions identified within this evaluation, the department determines that the application is consistent with the applicable need criteria in WAC 246-310-210.

- (1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need

The Department of Health's Certificate of Need Program uses the numeric methodology found in WAC 246-310-270 for determining the need for additional ASCs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient OR's in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 separate secondary health services planning areas. The exempt ASC, which will not relocate, is currently located in the city of Mount Vernon, within the east Skagit planning area. It is noted that the methodology identifies east Skagit as a planning area, which includes the entire county, with the exception of Fidalgo Island.

The numeric methodology estimates OR need in a planning area using multi-steps as defined in WAC 246-310-270(9). This methodology relies on several variables: surgical use rates in the planning area, projected population of the planning area, existing supply of OR capacity, and the average times of inpatient and outpatient surgeries in the area. Using these variables, the methodology determines existing capacity of dedicated outpatient and mixed-use operating rooms in the planning area, subtracts this capacity from the forecast number of surgeries to be expected in the planning area in the target year, and examines the difference to determine:

- a) whether a surplus or shortage of OR's is predicted to exist in the target year, and
- b) if a shortage of OR's is predicted, the shortage of dedicated outpatient and mixed-use rooms are calculated.

To determine need for additional ORs in the planning area under WAC 246-310-270, the applicant relied on the variables or assumptions shown below.

Variables/Assumptions	Data Used
Planning Area	East Skagit County, plus one zip code in Snohomish County, resulting in 94.85% of the total Skagit County population.
Population Estimates and Forecasts/Target Year	Using OFM population data released January 2000 and based on target year 2008.
Use Rate	Based on 1994 FASCAW ³ data, the use rate of 102/1,000 was applied to year 2005 and the projected 2005 population results in the planning area identified above.
Percent of surgery: ambulatory vs. inpatient	72.3% ambulatory setting; 27.8% inpatient setting
Average minutes per case	Outpatient cases = 50 minutes; inpatient cases 100 minutes
Annual OR capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes

³ Freestanding Ambulatory Surgery Centers of Washington, a nonprofit organization founded in 1993. More information can be found at www.fascaw.org

The applicant's methodology resulted in a projected need for one mixed-use OR and six dedicated outpatient ORs for year 2008. [source: Application, pp14-17; Attachments IV-3 & 5]

The exempt ASC is currently located in east Skagit planning area, which includes all of Skagit County, with the exception of Fidalgo Island. There are six providers in the east Skagit planning area-two hospitals and four ASCs. The six providers are listed below. [source: CN historical files-FSL database]

Table I
East Skagit Planning Area Providers

2 Hospitals / City	4 ASCs / City
Skagit Valley Hospital / Mt. Vernon	North Cascade ENT & Facial Plastic Surgery / Mt Vernon
United General Hospital / Sedro Woolley	North Cascade Foot Clinic / Mt. Vernon
	Northwest Orthopedic Surgeons, PS / Mt. Vernon
	Skagit Island Orthopedic (the applicant) / Mt. Vernon

As shown in Table I above, the six facilities include two hospitals and four ASCs, including the ASC associated with this project. Of the two hospitals, all have inpatient and outpatient capacity. The ORs for both hospitals will be included in the count of capacity in the east Skagit planning area.

Of the four ASCs shown in Table I, all are located within a solo or group practice, and therefore, the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. These four facilities do not meet the ASC definition found in WAC 246-310-010, therefore, the ORs within those facilities will not be included in the capacity calculations of available ORs for the east Skagit planning area.

To assist in its application of the numeric methodology for this project, in April 2006, the department requested utilization information from each of the six facilities identified above. Responses were received from both of the hospitals and only one exempt ASC.⁴ Additionally, the applicant's data provided in the application was used to apply the numeric methodology. The department also relied on the following variables/assumptions to apply its methodology.

Variables/Assumptions	Data Used
Planning Area	East Skagit County, resulting in 72.3% of the Skagit County population.
Population Estimates and Forecasts/Target Year	Using OFM population data released June 29, 2006 and based on target year 2009.
Use Rate	Based on utilization surveys in the planning area, the use rate of 114.59/1,000 was applied to year 2005 and projected 2009 population.
Variables/Assumptions	Data Used
Percent of surgery: ambulatory vs. inpatient	72.3% ambulatory setting; 27.8% inpatient setting
Average minutes per case	Outpatient cases = 60 minutes; inpatient cases 108.24 minutes
Annual OR capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes

⁴ North Cascade ENT & Facial Plastic Surgery submitted its response.

The department typically also relies on survey information to determine the available supply of operating rooms in a planning area. In its survey and documents provided during the public comment and rebuttal periods of this review, United General Hospital in Sedro Woolley indicated that it currently has 3 mixed-use OR that are unutilized. [source: UGH survey data] At the invitation of United General Hospital, Certificate of Need staff toured the hospital on September 16, 2002. The tour verified that the hospital, indeed, has three ORs. Of those three, one OR was dedicated exclusively to eye surgery, and the remaining two were unequipped and unused. In fact, at the time of the tour, the two unused ORs were used as storage space. [source: CN historical files] Regarding the two unused ORs at United General Hospital, before an OR currently used for storage may be converted back to OR use, prior construction review and survey by the department's Construction Review Unit is required. Data obtained from the Construction Review Unit indicates that a request for review or survey for this type of project has not been submitted by United General Hospital. Therefore, without information to confirm otherwise, the department must conclude that the two remaining ORs continue to be unequipped for use. As a result, two of the three ORs at United General Hospital are unavailable for use by any entity, including the hospital. When applying the numeric methodology, the department counts the one available OR at United General Hospital.

Using the variables and assumptions above and the department's count of available ORs in the east Skagit planning area, the department's application of the numeric methodology indicates a surplus of 2.76 mixed use ORs and a shortage of 6.18 outpatient ORs for the planning area in year 2009. The department's numeric methodology is Appendix A attached to this evaluation.

When comparing the applicant's projections (need for 1 mixed use OR and 6 dedicated outpatient ORs) and the department's projections, the difference in results can be attributed to the following four factors discussed below.

1) Planning Area

As previously stated, the methodology separates Washington State into 54 separate secondary health services planning areas. This project is located within the east Skagit planning area, which includes the entire county, with the exception of Fidalgo Island. The applicant inadvertently included one zip code and corresponding population for Snohomish County (98296). By including this Snohomish county zip code, the applicant concluded that east Skagit County planning area was 94.85% of the entire Skagit County population. When the department excluded the Snohomish County zip code and population, the east Skagit County planning area is 72.3% of the Skagit County population.

2) Population Estimates/Forecasts and Target Year

When this application was submitted, the most recent population data obtained from the Office of Financial Management (OFM) was January 2000. On June 29, 2006, OFM released its updated population projection estimates. The updated estimates revealed that Skagit County's January 2000 population estimates were overstated by approximately 2,236 persons for year 2005.⁵ The department used the most recent OFM data when evaluating this project. The department uses the applicant's third year of operation as its target year. For this project, year 2009 is the facility's third full year of operation. It is unclear why the applicant chose year 2008—the facility's second full year of operation—as its target year.

⁵ January 2000 projected year 2005 population in Skagit County to be 113,136; June 29, 2006, projected 2005 population to be 110,900.

3) Use Rate

The use rate used by the applicant in its projections is based on 1994 FASCAW data; the use rate of 102/1,000 was applied to the projected 2008 population results in the planning area. Based on utilization survey results provided by the providers in the east Skagit planning area, the department applied the higher use rate of 114.59.

4) Average Minutes per Case

The applicant used the default average minutes per case stated within the methodology. This default—50 minutes per outpatient and 100 minutes per inpatient—is used when data is unavailable. Based on utilization survey results provided by the providers in the east Skagit planning area, the department used 60 minutes per outpatient and 108.24 per inpatient.

In summary, the department's methodology results in a surplus of 2.76 mixed use ORs and a shortage of 6.18 outpatient ORs for the east Skagit planning area in year 2009.

Skagit Valley Hospital (SVH) in Mount Vernon provided concerns related to the applicant's methodology (WAC 246-310-270). The concerns focused on the applicant's inclusion of the Snohomish County zip code and corresponding population within its methodology. [source: Skagit Valley Hospital, May 30, 2006, public hearing documents] Given that the department did not adopt the applicant's methodology, rather it relied on the assumptions outlined above to apply its own methodology under WAC 246-310-270, and relied on those results within this evaluation, SVH's concerns have been addressed.

To further demonstrate compliance with the need criterion under WAC 246-310-210, the applicant provided the following assertions. [source: Application: pp18-19]

"Growth in the service area has steadily increased. In 1990, the Skagit County population totaled 79,545. In the Year 2000, the population grew to 102,979 residents. In the east Skagit planning area, for the year 2000, the population was estimated at 97,671, or 94.85% of the Skagit County population. By the year 2010, the Skagit County population is expected to increase to 123,807."

This is an existing facility, and as such, the physicians no longer have significant delays in the ASC setting. However, as previously discussed, delays between cases had caused on-going productivity lapses. In addition, co-mingling of acute and emergent with planned outpatient surgeries led to long delays in the OR. Patients complained of 'nothing by mouth' [i.e. food or drink], then being 'bumped' for more emergent cases. This is a particular hardship for diabetic patients."

Concerns raised in opposition to this project related to this sub-criterion were provided by three hospitals located in Skagit County--Island Hospital in Anacortes; Skagit Valley Hospital in Mount Vernon, and United General Hospital in Sedro-Woolley. Those concerns are restated below.

- *"Island Hospital has four modern, completely appointed and staffed surgical suites, which are underutilized at the present time. Our utilization statistics show 42% of available OR time was booked Monday-Friday, 0800 to 1700 in 2003, and only 36% of the same time periods were utilized during 2005. The opening of Skagit Island Orthopedic Surgical Center in Mount Vernon has had significant negative impact for Island Hospital and we have seen our outpatient surgery decrease by more than 70%. Adding the ability to perform other types of surgeries at the*

outpatient center will further deteriorate our outpatient surgical business and we ask that this Certificate of Need not be approved.”

[source: May 25, 2006, public comments and Utilization Survey comments]

- *“United General Hospital is currently working diligently to expand our services and have significant time in our 3 OR suites going unutilized. Nearly 50% of our cases are ophthalmology for which we have recently invested in capital equipment. We have also been attempting to expand our pain management and podiatry services as well. We are in need of orthopedic surgeons to see our current emergency room patients. We are equipped in our ORs with new power equipment as well as fracture sets to handle most orthopedic emergencies but cannot find local orthopedic surgeons willing to come over to perform the surgeries. Patients therefore get transferred to other facilities causing not only inconvenience, but also additional healthcare dollars spent on ambulance transfers and emergency department visits. ...As a district hospital, we are supported by community dollars, which can be used more efficiently as the number of cases we perform increases.”*

[source: United General Hospital, May 26, 2006, utilization survey and public comments]

- Skagit Valley Hospital -- within its utilization survey responses, Skagit Valley Hospital provided a table showing the estimated loss of surgeries for the hospital if this project is approved. The table indicates a loss in orthopedic, podiatry, and ophthalmologic cases for the applicant's projected years 2007 through 2010. The hospital estimates a total overall loss of 6% of its cases, which equates to a \$669,833 loss in gross revenue in year 2007 that increases to a \$974,218 loss in gross revenue in year 2010. [source: SVH utilization survey responses]

Applicant's response to concerns

PS, Inc. did not provide any response to the concerns raised by United General Hospital.

In response to the concerns raised by Island Hospital in Anacortes, the applicant provided the following statements. [source: June 14, 2006, rebuttal documents, pp1-3]

“Island Hospital contends their outpatient surgery has decreased by more than 70% since Skagit Valley Orthopedic opened their facility in 2003. According to the Island Hospital [utilization] survey data outpatient volumes were reported as follows—2003=3,183 procedures; 2004=2,872 procedures; 2005=3,024 procedures. Using their own data, there would appear to be a decrease of 159 outpatient procedures from 2003 to 2005, or a 5% decrease, not the 70% reported.

In response to the concerns raised by Skagit Valley Hospital in Mount Vernon, the applicant provided the following statements. [source: June 14, 2006, rebuttal documents, p7]

Skagit Valley Hospital...echoed the same financial concerns as Island Hospital stating ‘As noted in SVH's response to the CON Program's ASC survey for Skagit county, opening the Skagit Island Orthopedic Surgery Center to other physicians will have a financial impact on SVH.’ The applicant would again offer Washington State DOH Center for Health Statistics-Hospital Data showing that SVH posted a 2004 operating income of \$4, 026,141. Again this does not appear to be a hospital at financial risk; they also seem to have weathered the opening of the Applicants facility in July of 2003.” [attachments provided to the rebuttal comments]

Department's evaluation of the concerns

The representative of United General Hospital indicates that it is “*working diligently to expand our services and have significant time in our 3 operating room suites going unutilized.*” The hospital indicates that it has a total of three ORs, and on this basis, United General Hospital concludes that there is a surplus of ORs in the county. [source: United General Hospital utilization survey] The number of available ORs at United General Hospital was discussed earlier in this evaluation.

The department's Office of Hospital and Patient Data Systems (OHPDS) collects Comprehensive Hospital Abstract Reporting System (CHARS) data reported by the hospitals in Washington State. The data is reported to OHPDS by each hospital on a quarterly basis. A review of United General Hospital's reported ambulatory surgery cases by quarter for year 2005 reveals that the number of ambulatory surgery cases has slightly increased from 278 cases in the first quarter, to 338 in quarter two, to 345 in the third quarter, and 347 cases in the fourth quarter. Full year 2005 data shows a total of 1,208 cases. [source: CHARS data, January 1, 2005 through December 31, 2005] The quarterly reported data from the hospital indicates that the number of ambulatory surgery cases is increasing.

United General Hospital states within its utilization survey that it only performs ophthalmologic surgeries in its one utilized OR. Table III on page ??? of this evaluation shows the number of surgeries, by type, projected at Skagit Island Orthopedic Center. For ophthalmologic cases, PS, Inc projects 750 cases in year 2007, 773 in year 2008, and 796 in year 2009, equating to a 3% increase in the second and third years of operation.

Documents provided within this application indicate that physicians associated with Skagit Island Orthopedic Surgery center currently do not have surgical privileges at United General Hospital. As a result, the department must conclude that the exempt ASC did not have an impact on the viability of the hospital, and approval of this project would also not affect the hospital's viability.

Regarding Island Hospital's concerns, as previously stated, the numeric methodology found in WAC 246-310-270 divides the 39 counties in Washington State into 54 separate planning areas. Portions of Skagit County are included in two different planning areas:

- 1) east Skagit planning area--encompasses all of Skagit County, with the exception of Fidalgo Island; and
- 2) Whidbey-Fidalgo Island planning area--encompasses all of Island County and Fidalgo Island in Skagit County. The city of Anacortes is located on Fidalgo Island.

Island Hospital is located in Anacortes, within the Whidbey-Fidalgo Island planning area, which adjacent to the east Skagit Planning area. The number of ORs and the utilization of those ORs would not be considered in this evaluation. As a result, the department will not respond to Island Hospital's statements above.

To assist in its evaluation of whether the Skagit Valley Hospital's expected loss of cases would have a substantial negative effect, staff reviewed historical reported ambulatory surgery visits by quarter for year 2005. [source: CHARS data, January 1, 2005 through December 31, 2005] The data, however, appears to be reported incorrectly by the hospital because the data reveals that Skagit Valley Hospital had zero ambulatory surgery visits in all four quarters of year 2005. As a result, staff is unable to verify the hospital's assertions that approval of this project would decrease its number of ambulatory surgery visits.

A review of Skagit Valley Hospital's quarterly financial data reported for year 2005 shows that the hospital's 2005 operating margin of approximately \$10 million. As a result, while approval of this project is expected to affect the hospital's number of cases and gross revenues, it is not expected to jeopardize Skagit Valley Hospital's operating margin.

In summary, information within the application and data reviewed by the department indicates that need for additional OR capacity in the east Skagit planning area is demonstrated. This conclusion is further supported when the department applies the numeric methodology using the actual number of available ORs in the east Skagit planning area. Using six available ORs--five at Skagit Valley Hospital and one at United General Hospital--the numeric methodology projects a need for 6.17 outpatient ORs. This project requests approval for two ORs in the planning area. Based on information provided within the application, this sub-criterion is met.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

As previously stated, PS, Inc owns and/or operates six ASCs in Washington State. Through these ASCs, PS, Inc has provided health care services to residents of the respective service areas. To demonstrate compliance with this criterion, the applicant provided a copy of Skagit Island Orthopedic Surgery Center's Admissions Policy, Patient's Rights and Responsibilities Policy, and Charity Care Policy [sources: as noted] The department's review of all three policies follows.

Admissions Policy [source: Application, Attachment III-4]

The Admission Policy outlines the process that the surgical center will use to admit patients and provides the overall guiding principles of the ASC as to the types of patients that are appropriate candidates to use the ASC. It also intended to ensure that patients will receive the appropriate surgical intervention at the ASC. The department concludes that the information contained in this policy appropriately identifies the types of patients that would be eligible for services at the ASC and prerequisites the patient must meet before having a procedure at the proposed ASC. Omitted from this document is the assurance that all patients, including low-income, racial and ethnic minorities, handicapped and other underserved groups would have access to surgical services. If this project is approved, the department would attach a term to the approval requiring PS, Inc. to submit a revised Admission Policy for Skagit Island Orthopedic Center with the required language that ensures all patients, including low-income, racial and ethnic minorities, handicapped and other underserved groups would have access to surgical services.

Patient's Rights and Responsibilities Policy [source: Application, Attachment IV-8]

This policy ensures the patient's ability to receive confidential care and treatment appropriate to the diagnosis, and the ability to participate actively in decisions regarding medical care provided. The policy also ensures that all patients would be admitted to the ASC without regard to age, race, color, religion, sex, national origin, handicap, or sexual preference and will be treated with respect and dignity.

Charity Care Policy [source: April 17, 2006, supplemental information, Attachment 1]

The Charity Care Policy provided in the application outlines the process to be used for patients to access financial assistance to pay for services provided at the ASC.

To determine whether low income residents would have access to the ASC, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. According to data obtained from the PS, Inc. website, on December 2, 2002, Proliance Surgeons announced its formal resignation from the Medicaid program. Documentation provided in the application indicates that the six PS, Inc. practices with an exempt ASC may elect to participate in the Medicaid program even though the larger PS, Inc. does not. Information provided by the applicant verifies that Skagit Island Orthopedic Center established its Medicaid contract on September 26, 2005. Further, within the application, PS, Inc. provided the projected sources of revenues at Skagit Island Orthopedic Center, which includes Medicare and Medicaid as revenue sources. Given that PS, Inc.'s general position is not to contract with Medicaid, if this project is approved, the department would attach a condition to the approval requiring Skagit Island Orthopedic Surgery Center to maintain its Medicaid participation. [source: April 17, 2006, supplemental information, p4; May 1, 2006, supplemental information, Attachment 1]

WAC 246-310-270(7) states that ASCs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. For charity care reporting purposes, the Department of Health's Office of Hospital and Patient Data Systems (OHPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Skagit Island Orthopedic Surgery Center is located in east Skagit planning area within the Puget Sound Region.

There are 18 existing hospitals currently operating within the Puget Sound Region, and of those two hospitals are located in the east Skagit planning area that would be affected by the proposed ASC-- Skagit Valley Hospital in Mount Vernon and United General Hospital in Sedro Woolley. For this project, the department reviewed charity care data for all 18 hospitals in the region and both hospitals located in the applicant's planning area.

For years 2002 and 2003, both hospitals were operated under Affiliated Health Services. On January 1, 2004, Affiliated Health Services dissolved, and each hospital began to operate separately. The table below shows the historical charity care percentages for Affiliated Health Services in years 2002 and 2003, and each hospital's data for year 2004.

Tables II
Years 2002 and 2004 Puget Sound Region-Charity Care Percentages

Year	Percentage of Total Revenue	Percentage of Adjusted Revenue
2002	0.89%	1.77%
2003	1.14%	2.29%
2004	1.82%	3.80%
3 Year Average	1.28%	2.62%

Years 2002 and 2003 Affiliated Health Services-Charity Care Percentages

Year	Percentage of Total Revenue	Percentage of Adjusted Revenue
2002	0.68%	1.39%
2003	1.96%	4.07%
2 Year Average	1.32%	2.73%

Year 2004 Skagit Valley Hospital-Charity Care Percentages

Year	Percentage of Total Revenue	Percentage of Adjusted Revenue
2004	2.04%	4.34%

Year 2004 United General Hospital-Charity Care Percentages

Year	Percentage of Total Revenue	Percentage of Adjusted Revenue
2004	2.20%	4.44%

Three Year Average for Both Hospitals-Charity Care Percentages

Year	Percentage of Total Revenue	Percentage of Adjusted Revenue
2002-2004	1.61	3.36%

The applicant's pro formas indicate that the ASC will provide charity care at approximately 2% of gross revenue, and 4.74% of adjusted revenue. [source: Application, p10; & April 17, 2006, supplemental information, p4] The projected averages are better than the average charity care provided in the Puget Sound Region, and better than the two year average provided by Affiliated Health Services and the combined three-year average for both hospitals. To ensure the applicant would continue to meet its charity care obligations as required in WAC 246-310-270, if this project is approved, the department concludes that a condition related to the charity care to be provided at the ASC is necessary.

The department concludes that any approval of this project must include the following term:

Before commencement of the project, Proliance Surgeons, Inc. must provide to the department for review and approval a copy of the revised Admissions Policy for Skagit Island Orthopedic Center. The revised policy must include language ensuring all patients, including low-income, racial and ethnic minorities, handicapped and other underserved groups would have access to surgical services.

Additionally, the department concludes that any approval of this project must include the following conditions:

1. Proliance Surgeons, Inc. will ensure that Skagit Island Orthopedic Surgery Center will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. Skagit Island Orthopedic Surgery Center will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by the two hospitals located in the east Skagit planning area during the three most recent years. For historical years 2002-2004, these amounts are 1.61% of gross revenues and 3.36% of adjusted revenues. Skagit Island Orthopedic Surgery Center will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies and applicable law.
2. Skagit Island Orthopedic Surgery Center will maintain its participation in the Medicaid Program by maintaining its existing contract with Department of Socials and Health Services.

Provided the applicant agrees to the above term and conditions, this sub-criterion is considered met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed and subject to the term and conditions identified within this evaluation, the department determines that the application is consistent with the applicable financial feasibility criteria in WAC 246-310-220.

(1) *The immediate and long-range capital and operating costs of the project can be met.*

Historical CN files confirm that Skagit Island Orthopedic Surgery Center became operational as an exempt ASC in September 2003. Table II below shows the projected number of surgeries, which includes podiatry, pain management, and ophthalmology. [source: Application, p4 & Attachment III-10; and April 17, 2006, supplemental information, p4]

Table III
Skagit Island Orthopedic Center Projected Number of Surgeries by Type

	Partial Year 2006	Year 1-2007	Year 2-2008	Year 3-2009
Orthopedic	1,296	1,335	1,375	1,416
Podiatry	100	200	206	212
Pain Management	200	400	412	424
Ophthalmology	375	750	773	796
Totals	1,971	2,685	2,766	2,848

As shown in Table III above, PS projects a 3% increase in the total projected number of surgeries from year one to year two; and again from year two to three. The applicant provided the following rationale for the projections above.

“For 2006, assumptions were based on a half year of use—pending CON approval. For the first full year, no increase was included. For the subsequent three years of operation (2008 through 2010) conservative utilization assumptions were made using only a three percent annual increase to utilization. These assumptions are conservative.”

[source: April 17, 2006, supplemental information, p3]

To determine whether the ASC would meet its immediate and long range operating costs, the department evaluated Skagit Island Orthopedic Surgery Center’s projected balance sheets through the project’s third full year of operation (2009). A summary of the balance sheets for the ASC’s first three full years of operation is shown below and continued on the following page. [source: Application, Attachment IV-11 & April 17, 2006, supplement information]

Tables IV
Skagit Island Orthopedic Surgery Center Balance Sheets for Years 2005-2007
Year 2007

Assets		Liabilities	
Current Assets	\$ 454,475	Current Liabilities	\$ 266,800
Fixed Assets	787,632	Other Liabilities (long term debt)	691,253
Other Assets	617,292	Total Liabilities	\$ 958,053
Total Assets	\$ 1,859,399	Equity	\$ 901,347
		Total Liabilities and Equity	\$ 1,859,399

Year 2008			
Assets		Liabilities	
Current Assets	\$ 596,443	Current Liabilities	\$ 285,913
Fixed Assets	794,832	Other Liabilities (long term debt)	411,770
Other Assets	341,938	Total Liabilities	\$ 697,683
Total Assets	\$ 1,733,213	Equity	1,035,530
		Total Liabilities and Equity	\$ 1,733,213

Year 2009			
Assets		Liabilities	
Current Assets	\$ 720,871	Current Liabilities	\$ 306,506
Fixed Assets	797,206	Other Liabilities (long term debt)	411,770
Other Assets	16,585	Total Liabilities	\$ 718,276
Total Assets	\$ 1,534,662	Equity	816,386
		Total Liabilities and Equity	\$ 1,534,662

Based on the projected balance sheets, it is clear that Skagit Island Orthopedic Surgery Center would be a financially stable ASC. Further, a review of the balance sheets provided in the application indicates that the ASC intends to acquire very little long term debt for this project.

Additionally, the ASC's debt service coverage is considered well above the average due to the applicant's intent to pay off its debt fairly quickly. While this approach by the applicant is ambitious, it is not an unusual approach for an ASC.

Based on the financial information above, the department concludes that the long-term capital and operating costs of this project can be met, and this sub-criterion is satisfied.

- (2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

Table V below details the projected revenues and expenses for Skagit Island Orthopedic Surgery Center's first three full years of operation based on the projected number of surgeries shown in Table III of this evaluation. [source: Application, Attachment III-10 & IV-6-1, and April 17, 2006, supplemental information, p4]

Table V
Skagit Island Orthopedic Surgery Center Revenue and Expense Summary
Projected Years 2005 through 2007

	Full Year 1 (2007)	Full Year 2 (2008)	Full Year 3 (2009)
# of Surgeries	2,685	2,766	2,848
Net Patient Revenue*	\$ 1,901,009	\$ 1,958,038	\$ 2,016,780
Total Expense	\$ 1,694,572	\$ 1,748,721	\$ 1,805,056
Net Profit or (Loss)	\$ 206,437	\$ 209,317	\$ 211,724
Net Revenue per Surgery	\$ 708.01	\$ 707.90	\$ 708.14
Total Expenses per Surgery	\$ 631.13	\$ 632.22	\$ 633.80
Net Profit or (Loss) per Surgery	\$ 76.89	\$ 75.67	\$ 74.34

*Includes deductions for bad debt, charity care, and contractual write-offs

As noted in Table V, the ASC would be operating at a profit through the first three years of operation, and the profit does not substantially increase or decrease in each of those three years.

In addition to the pro forma projections provided above, PS, Inc also provided the following statements related to the assumptions used as a basis for the projections at the ASC. [source: April 17, 2006, supplemental information, p3]

“For 2006, assumptions were based on a half year of use--pending CON approval. For the first full year [2007], no increase was included. For the subsequent three years of operations [2008-2010], conservative utilization assumptions were made using only a three percent annual increase of utilization. The assumptions are conservative.”

Documents provided in the application, indicate that the Skagit Island Orthopedic Center would offer surgeries in orthopedic, podiatry, and ophthalmology, and include some pain management procedures. Further, in the project description portion of this evaluation, the department notes that the ASC anticipates recruitment of an ENT and plastic surgeons, in addition to the projections above. Data within the application supports the applicant’s assertions that projected number of surgeries are conservative.

CN program staff also compared the projected costs and charges above to those of recent ASC applications. That comparison reveals that the costs and charges identified above are comparable to those shown in like-type ASC applications.

Based on the information provided above, the department concludes that the cost of the project will not result in an unreasonable impact on the costs and charges for health services within the service area. This sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed and subject to the term and conditions identified within this evaluation, the department determines that the application is consistent with the applicable structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

Given that the ASC is currently operating, the applicant anticipates a minimal increase in staff if this project is approved. Any increase in staff would be based on the increase in surgeries at the ASC. Table VI on the following page summarizes the current and projected staffing of Skagit Island Orthopedic Surgery Center. [source: Application, p31]

Table VI
Skagit Island Orthopedic Surgery Center - Current and Projected Staffing

Current and Projected Staffing	Current	Year 1 - Increase	Year 2- Increase	Year 3 - Increase	Total
Nurse Director	1	0	0	0	1
Pre-Op / Recovery (RN / LPN)	2	0	1	0	3
Circulate RN	2	0	1	0	3
Scrub Technician	1	1	0	0	2
Float RN	1	0	1	0	2
Central Service Technician	1	0	1	0	2
Patient Education	0	1	0	0	1
Medical Records Clerk	1	0	0	0	1
Scheduling Secretary/Admission Reception	2	0	0	0	2
Administration	1	0	0	0	1
Total FTEs	12	2	4	0	18

As shown above in Table VI, the applicant anticipates a small increase in FTEs for years one and two, and no increase in year three. The applicant also states that the surgeries, and therefore the staff, of the existing ASC have continued to grow since opening the facility in 2003. Given the small FTE increase, existing staff that desire continued employment at the ASC will be accommodated, and any vacancies will be filled via advertising. [source: Application, pp31-33]

Because PS, Inc will continue to have ownership in the facility, it is a reasonable assumption that many, if not all, of the current staff of the ASC will remain employed by the ASC if this project is approved. The department concludes that it is reasonable and prudent for the applicant to transfer current staff to the ASC to ensure adequate staffing for the ASC.

Based on the information provided in the application, the department concludes that PS, Inc provided a comprehensive approach to recruit and retain staff necessary for the ASC. This sub-criterion is met.

- (2) *The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.*

Given that Skagit Island Orthopedic Surgery Center is currently operating as an exempt ASC, ancillary and support agreements are already in place. To demonstrate compliance with this sub-criterion, the applicant provided copies of its existing service contracts and/or agreements. Below is a summary of the types of agreements provided. [source: Application, Attachments III-6, III-7, III-9 & IV-13]

- Ancillary Service Agreements, including equipment, anesthesia, linen, medical waste, and pharmaceutical
- Patient Transfer Agreement with Skagit Valley Hospital
- Patient Transportation Agreements w/ local medical transportation companies
- Medical Director Job Description (not a contracted or compensated position)

After reviewing the documents above, the department concludes that the applicant has demonstrated compliance with this sub-criterion. This sub-criterion is met.

- (3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*

As stated in the project description portion of this evaluation, the applicant, PS, Inc., operates six ASCs, including the ASC associated with this project. The Department of Health's Office of Health Care Survey (OHCS), which surveys ASCs within Washington State, has completed a total of eleven compliance surveys for the PS, Inc. facilities.⁶ Of the six facilities, three had no deficiencies and three were cited for minor non-compliance issues. The non-compliance issues were typical for the type of facility and PS, Inc. submitted a plan of corrections and implemented the required corrections. [source: compliance survey data provided by Office of Health Care Survey]

PS, Inc. identified Curtis Rodin, MD as the current and proposed medical director for the ASC and provided a listing of current credentialed or licensed staff of the ASC. The Department of Health's Medical Quality Assurance Commission credentials all staff in Washington State. A review of the compliance history for the medical director and existing staff reveals no recorded sanctions for all. [source: compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of all of the ASC 's owned and/or operated by PS, Inc and the compliance history of the medical director and staff currently associated with the ASC, there is reasonable assurance that PS, Inc. would continue to operate the ASC in conformance with applicable state and federal licensing and certification requirements. This sub-criterion is met.

- (4) *The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.*

As noted earlier in this evaluation, the existing ASC is already operating as an exempt ASC, therefore, Skagit Island Orthopedic Surgery Center already has established relationships with the existing health care system.

As previously stated in the need portions of this evaluation, PS, Inc. has withdrawn from participation in the Medicaid program as of November 2002. However, documentation provided in the application indicates that the six PS, Inc. practices with an exempt ASC may elect to participate in the Medicaid program even though the larger PS, Inc. does not. Information provided by PS, Inc. verifies that Skagit Island Orthopedic Center established its Medicaid contract on September 26, 2005. Given that PS, Inc.'s general position is not to contract with Medicaid, the department concluded that any approval of this project would include a condition requiring Skagit Island Orthopedic Surgery Center to maintain its Medicaid participation.

After reviewing the information above, the department concludes that the applicant demonstrated its existing relationships with ancillary and support services for the health care services are appropriate. Additionally, the applicant currently meets all of the necessary documentation required for the operation and management of the ASC. With the applicant's agreement to the condition requiring Skagit Island Orthopedic Surgery Center to maintain its Medicaid participation, approval of this

⁶ Surveys conducted: Evergreen Orthopedic Surgery Center-2003; Evergreen Surgical Clinic-1994, 1998, and 2002; Issaquah Surgery Center-2004; Valley Orthopedic Associates Surgery Center-1999 and 2005; Edmonds Center for Outpatient Surgery-1992, 1996, and 2003; Skagit Island Orthopedic Surgery Center-2003.

project would not result in an unwarranted fragmentation of services, and this sub-criterion would be met.

- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This sub-criterion is evaluated in sub-section (3) above, and based on that evaluation, the department concludes that this sub-criterion is met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed and subject to the term and conditions identified within this evaluation, the department determines that the application is consistent with the applicable cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

The applicant states that its decision to proceed with this project was made after reviewing several key criteria and determining that the project was warranted. Key considerations identified by the applicant and related to this sub-criterion are restated below:

- Cost - dramatically increasing patient costs, such as premiums and co-pays, are forcing today's healthcare consumers to seek more cost-effective alternatives. The increased availability of "Part B" outpatient facilities can represent significant savings to the consumer.
- Joint Ventures - historically, it has been difficult for physicians and hospital to partner on projects of this type. There are a variety of economic, regulatory, practical, and cultural reasons why these arrangements don't work well. The applicant had a number of failed local examples to draw upon in electing to not consider a joint venture with area hospitals.
- Legal Restrictions - the applicant reviewed this project from a variety of legal perspectives. At the federal level, the recent establishment of the "safe-harbor" for physician owned surgery center would almost appear to encourage the development of these facilities..

[source: Application, pp33-34]

The applicant also contends that this project does not require any additional capital costs if approved and the project would improve system efficiencies because conversion of this exempt facility to a CN approved facility will insure that physicians who wish access to a facility of this type would have that option. Further, the applicant asserts that physician owned ASCs are one of the few attractive "talking-points" when recruiting new physicians to Washington State. The opportunity to have ownership in efficient, outpatient ancillaries, such as ASCs, and the revenue from those ancillaries is critical when trying to attract new physicians. The applicant further states that if approved, this ASC would be the only physician-owned ASC in the planning area. [source: Application, pp34]

In the need portion of this evaluation, the department concluded that PS, Inc. demonstrated need for the additional ORs, and the project met the criteria within financial feasibility and structure and process of care.

In summary, the department concludes that the applicant chose the one of the best available options for the patients and the community. Based on the information provided above, the department concludes that this project is consistent with this sub-criterion.